AUG 3 0 2001

K011983

Insight Genesis

510(k) Summary

Submitted by:

Company Name:	Fasstech
Company Address #1:	155 Middlesex Turnpike
Company Address #2:	Burlington, MA 01803
Contact Person:	Lee Brody
Phone Number:	781.229.1500
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Submitted on: June 25, 2001

NE/4

5K2

Section 1: Device Name

Common or Usual Name: Biofeedback Device
Proprietary Model Name: Insight Genesis

Section 2: Indications for Use

- To measure bilateral differences in surface EMG along the spine
- To measure surface EMG along the spine during functional tasks
- To chart patient progress during the course of treatment

Section 3: Device Description

The Insight Genesis is a non-invasive, single-modality physiologic monitoring device. The Insight Genesis contains two surface EMG sensors used to measure muscle activity.

Hardware
The Insight Genesis hardware consists of an instrument console and two surface EMG sensors, which plug directly into the front panel of the Insight Instrument Console. The Insight Genesis Instrument Console is powered via a UL2601 listed wall mounted power supply. The Instrument Console is connected to a personal computer (IBM compatible) via an isolated serial port connection.

Software
The Insight Genesis software displays real-time surface EMG, allowing the user to ensure that readings are stable prior to data collection. The Insight Genesis software allows the user to: (1) enter patient information, (2) record surface EMG, (3) graph surface EMG, and (4) print out reports.

Section 4: Predicate Device

This section documents the substantial equivalence of the Insight Genesis to legally marketed devices. The Insight Genesis is a subset of the Insight Millennium (K990778). The Insight Millennium is a multi-modality device containing four surface EMG sensors, an infrared thermal scanner and an inclinometer. The Insight Genesis is a simplified version of the Insight Millennium and only contains two surface EMG sensors.

Fasstech Insight Millennium (K990778)

Feature	**Insight Genesis**	Insight Millennium
Two Channels of surface EMG for Static EMG	**Yes**	Yes
Two Channels of surface EMG for Dynamic EMG	**Yes**	Yes
Additional two channels of surface EMG for Dynamic EMG	**No**	Yes
Skin Temperature measurement via infrared thermal scanner	**No**	Yes
Range of Motion Sensor	**No**	Yes
UL-2601 listed wall-mounted power supply	**Yes**	Yes
Opto-isolated RS232 output	**Yes**	Yes
A/D Converter	**12 bit, 8 channel**	12 bit, 8 channel

Section 5: Performance Specification

EMG

Electrodes:	2 ea. Smart Sensors with low-noise preamplifiers integral to electrode assemblies
Calibrated Range:	0.1 – 999 uV
Input Bias Current:	Less than 2.0 Picoamperes
Differential Input Impedance:	Greater than 1,000,000 Megaohms
Common Mode Rejection:	150 dB
Bandwidth:	20-500 Hz (50/60 Hz notch)
Noise:	Less than 0.1 uV (inputs shorted)
Detector:	Log power detector, 250 mS averaging filter.
Controls:	None

Instrument Console

Inputs:	2 each EMG electrodes
Output:	Opto-isolated RS232 (9 pin sub-D jack)
A/D converter:	12 bit, 8 channel
Controls:	None
Power:	12V, 500 mA UL-2601 listed wall-mounted power supply.

Physical:	Case Material: Impact resistant, flame retardant ABS. 3.5"H x 8.375"W x 9"D. Weight 3 lbs. 11 oz.

Section 6: Patient Safety

The Insight Genesis patient safety is assured by the following design architecture:

Patient Isolation Circuitry: There are three primary components to the patient isolation circuitry: (a) an external plug-in medical-grade wall transformer. This device is a UL2601 listed wall transformer with an output of 12VDC and 500 mA max. There is also a 1A slow-blow fuse at the wall transformer input,(b) an industry standard DC-to-DC converter that meets the "dielectric withstand" and "leakage current" requirements of the UL2601 standard for Patient Care Equipment with isolated patient leads, and (c) the opto-isolation couplers described in Data Acquisition below.

Data Acquisition / RS232 Data Link: Processed signals are converted from analog voltages to 12 bit digital values by the analog-to-digital converter (ADC). The digital data is sent to and from the serial port of the PC across the isolation barrier via opto-coupler devices. The ADC and a portion of the RSR232 data link are on the patient side of the isolation barrier. The proper use of high voltage opto-couplers provides the dielectric withstand and low leakage current characteristics specified in UL2601. The non-isolated sides of the opto-couplers are then routed to RS232 drivers and receivers which are, in turn, routed to a DB9 connector at the rear panel of the Instrument Console. A standard RS232 serial cable connects the Instrument Console to the PC serial port.

Section 7: Conclusion

The Insight Genesis is substantially equivalent to the predicate device. Furthermore, the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Mr. Lee Brody
Chief Operating Officer
Fasstech
155 Middlesex Turnpike
Burlington, Massachusetts 01803

Re: K011983
Trade/Device Name: Insight Genesis
Regulation Number: 882.5050
Regulatory Class: II
Product Code: HCC
Dated: June 25, 2001
Received: June 26, 2001

Dear Mr. Brody:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walker, MD for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011983

Device Name: Insight Genesis

Indications for Use:

To measure bilateral differences in surface EMG along the spine
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011983